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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/963,243

09/26/2001

Curt R. Eyster

LIFE063

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06/20/2007

EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1743

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/963,243

Applicant(s)

EYSTER ET AL.

Examiner

Lyle A. Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/14/06;1/23/06</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1,5 and 10 are not clear where the reagent pad is affixed. The present language "... affixed to one of the top and bottom surfaces ..." is not clear if the pad is attached to the top surface or the bottom surface. As the office best understands the invention, the pad is attached to the bottom surface directly contacting the receiving aperture. Additionally, the language "... wherein at least a portion of a first surface integral with the surface on which the reagent pad is affixed thereto..." is confusing and could be clarified by using this alternative language -- ... wherein at least a portion of the bottom surface on which the reagent pad is affixed thereto ...--. Note that claim 2 states "bottom surface" which conforms to the language suggested by the Office.

Claims 3,7 and 11 are confusing what is the lower limit of the claimed sample volume range "less than or equal to 5 microliter". Will the device work with 1 nanoliter ? Also a volume of " zero " is within the claimed range. Minimally, Applicants' should state the volume is greater than zero and less than or equal to 5 microliters.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,5-7 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirayaja et al.

Hirayaja et al teach a test device and use with a colorimeter to make optical determinations from a color liquid such as blood. Figure 1 teaches a first surface(1) and an opposite surface(5) having an aperture(51) in surface(5) that receives the sample. In columns 5-6 lines 60 – 16 respectively teach the surface(5) can be black in color having a reflectance of 5.3% at a wavelength of 640 nm. The Office has read the claimed top layer on surface(1), the bottom layer on surface(5). Hirayaja et al. teach a sample size of 20 microliters.

Hirayaja et al. do not teach the reagent pad directly contacting the sample-receiving aperture. Rather, Hirayaja et al. provides a chamber(53) between the sample receiving aperture and the reagent pad. Hirayaja et al. is also silent to the claimed sample volume of "less than or equal to 5 microliter".

The Office is interpreting the chamber(53) taught by Hirayaja et al. as an element of the device. The court decided that the omission of an element and retention of its function is indicia of unobviousness. (see "MPEP 2144 II B" that summaries the decision In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966)). Additionally, it is desirable to eliminate an element of a device, such as a chamber(53), to reduce the cost of producing the device.

It would have been within the skill of the art to modify Hirayaja et al. and eliminate chamber(53) placing the reagent pad in direct communication with the sample receiving aperture in view of Edge above and to gain the above advantages.

With respect to the claimed volume of the sample, the court decided In re Yount (80 USPQ 141) that the size of an article under consideration is not ordinarily a matter of invention. In this case the size of the device dictates the volume of sample that would be required (e.g. a larger device would require a larger sample, etc. ). Further, it is desirable in the field of analytical testing to use the minimal volume of sample to minimize the amount of sample needed. Smaller sample can be obtained in a more comfortable manner by finger prick as opposed vein puncture. Also the smaller sample obtained by finger prick do not need specialized technicians and can be done by the patient.

It would have been within the skill of the art to further modify Hirayaja et al. to require a smaller volume of blood, such as 5 microliter, to gain the above advantages of using a smaller sample in light of the teaching of Yount that size is not ordinarily a matter of invention.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirayaja et al in view of Phillips et al. (USP 5,843,692).

See Hirayaja et al. supra.

Hirayaja et al. is silent to the claimed use of a 5 microliter sample volume and a "notch" in the test strip.

Phillips et al. teach a test strip and spectrometer for the measurement of analytes in blood in the range of 635-700nm. In column 8 lines 5+ teach a preferred method of sample acquisition is by finger prick that results in a sample of 5-10 microliters of blood. Further in column 11 lines 9+ teach the test strip is optimally guided into the

spectrophotometer by using a notch(15). The notch is advantageous because the slide will consistently arrive at the same location to assure high reproducibility of test results. The notch is further advantageous because the user can not place the wrong end into the spectrometer and obtain a spurious result.

The court decided In re Yount (80 USPQ 141) that the size of an article under consideration is not ordinarily a matter of invention. In this case the size of the device dictates the volume of sample that would be required (e.g. a larger device would require a larger sample, etc. ). It is desirable in the field of analytical testing to use the minimal volume of sample to minimize the amount of sample needed. Smaller sample can be obtained in a more comfortable manner by finger prick as opposed vein puncture. Phillips et al. teach it is preferred to use a finger prick to obtain the sample in the volume range of 5-10 microliters.

It would have been within the skill of the art to modify Hirayaja et al. in view of Phillips et al. incorporate a notch and use a finger prick to collect a minimal blood volume of 5 microliters to gain the above advantages.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. alone or further in view of Hirayaja et al.

See Phillips et al. and Hirayaja et al. supra.

These Phillips et al. teach a reflectivity of from 0 to 100% and is silent to the specific reflectivity of less than 12%.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one

that has well known and predictable results. Phillips et al. teach reflectivity in the range of 0 to 100% and all of the taught range is a result effective variable because it is contemplated by the reference.

It would have been within the skill of the art to modify Phillips et al. and select a reflectivity range of less than about 12 % as optimization of a result effective variable.

Hirayaja et al. teaches in column 4 lines 64-67 that black is a preferred color because it absorbs light over a broad range of wavelengths and can be applied to simultaneous measurements of a plurality of items. Columns 5-6 lines 60 – 16 respectively teach the surface(5) a black surface will have a reflectance of 5.3% at a wavelength of 640 nm which reads on the claimed reflectivity of less than about 12% at wavelengths 600-730 nm .

It would have been within the skill of the art to modify Phillips et al. in view of Hirayaja et al. and use a black surface to gain the above advantages.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

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A handwritten signature in black ink, appearing to be 'Lyle A. Alexander', written in a cursive style.